

JUL 24 2003

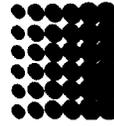
K 031090

Attachment - 6

## 510(k) Summary

THERICS, INC.  
115 CAMPUS DRIVE  
PRINCETON, NJ 08540  
TELEPHONE: 609-514-7200  
FAX: 609-514-7219  
E-MAIL: therics@therics.com

JUL 24 2003



1K031040  
THERICS

## 510(k) SUMMARY

### Therics' TheriFil™ Bone Void Filler

#### Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

##### Submitter's Name:

**Umberto V. Parrotta**

Telephone: 609.514.7237 or 609.514.7200 (main)

Facsimile: 609.514.7219

Contact Person: Umberto V. Parrotta

Date Prepared: March 31, 2003

#### Name of Device and Name/Address of Sponsor

##### TRADE/PROPRIETARY NAME OF DEVICE:

TheriFil™ Bone Void Filler

##### ADDRESS:

115 Campus Drive  
Princeton, New Jersey 08540

##### Common or Usual Name:

Bone Void Filler.  
Synthetic Bone Void Filler.  
Synthetic Cancellous Bone Void Filler.  
Bone Graft Substitute.  
Synthetic Bone Substitute.  
Synthetic Cancellous Bone Substitute

##### Classification Name

Bone Void Filler

##### Predicate Devices

Orthovita's Vitoss™

Wright Medical's WMT-TCP Bone Graft Substitute



**Intended Use / Indications for Use**

TheriFil™ Bone Void Filler is indicated for use in filling the gaps or voids of osseous defects surgically created or resulting from trauma and intended for treatment of osseous defects not intrinsic to the stability of the bone structure. The product is intended for use in defects of the skeletal system (i.e. the extremities, spine and pelvis). TheriFil™ parts create an interlocking network within the defect site that resorbs during healing and is replaced by bone.

**Technological Characteristics and Substantial Equivalence**

The TheriFil™ Bone Void Filler is constructed of synthetic β-tricalcium phosphate, a commonly found mineral in bone. The porosity and geometric features of β-tricalcium phosphate create an interlocking network within the defect site that resorbs during healing and is replaced by native bone.

A summary of the physical and chemical characteristics of both TheriFil™ and Vitoss™ is below in Table 1.

**Table 1. Physical characteristics of the TheriFil™ and Vitoss™ bone void fillers.**

Characteristic		TheriFil™	Vitoss™
Porosity		~60%	~80%
Pore Area (µm <sup>2</sup> )	Mean	3000 ± 1200	2700 ± 2200
	Min*	40	40
	Max	3.5x10 <sup>5</sup> ± 2.1x10 <sup>5</sup>	5.7x10 <sup>5</sup> ± 3.3x10 <sup>5</sup>
Pore diameter (µm)	Mean	60 ± 12	56 ± 19
	Min*	7	7
	Max	640 ± 220	810 ± 270
True Density (grams/mL)		1.530 ± 0.001	1.527 ± 0.002
Bulk Packing Density (grams/mL)		0.53 ± 0.02	0.22 ± 0.02
Packing Porosity (%)		65.7 ± 1.4	85.8 ± 1.0

Percent porosity and pore area (µm<sup>2</sup>) were estimated using SEM images (n = 30) and are described in *Attachment 13A, Porosity Characterization*. Data are shown as ave ± stdev. The pore diameter was estimated from the pore area by assuming circular shaped pores. \*All finite (< 40 µm<sup>2</sup>) pore structures were excluded from the analysis and therefore the minimum pore area is represented by 40µm<sup>2</sup> and the pore diameter by 7µm. The true density was measured using a pycnometer. Methods describing bulk packing density and packing porosity and described in *Attachment - 13B, Implant Packing Characterization*.

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Pre-clinical performance testing conducted on TheriFil™ and Vitoss™ in a canine animal model according to indication yielded similar results based on tissue reaction, bone ingrowth, residual material, and mechanical testing.

The TheriFil™ implants have the same intended use and indications, the same or similar principals of operation and technological characteristics, and equivalent performance in an appropriate animal model. Therefore, Theric's TheriFil™ Bone Void Filler is substantially equivalent to the predicate device.



JUL 24 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Umberto V. Parrotta, Jr.  
115 Campus Drive  
Therics, Inc.  
Princeton, NJ 08540

Re: K031040  
Trade Name: TheriFil Bone Void Filler  
Regulation Number: 21 CFR 888.3045  
Regulation Name: Resorbable calcium salt bone void filler device  
Regulatory Class: Class II  
Product Code: MQV  
Dated: March 31, 2003  
Received: April 1, 2003

Dear Mr. Parrotta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

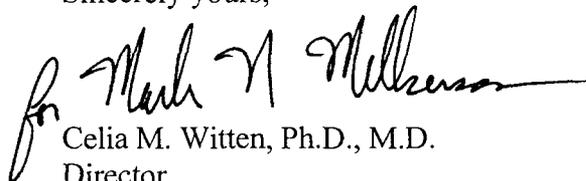
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050

Page 2 – Mr. Umberto V. Parrotta, Jr.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark N. Witten", is written over the typed name of the signatory.

Celia M. Witten, Ph.D., M.D.  
Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



CONFIDENTIAL

Attachment - 12

Indications for Use Form

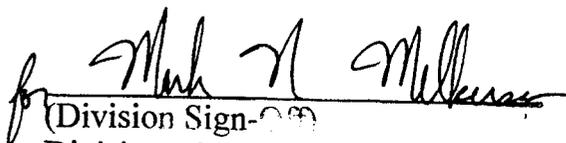
510(k) Number (if known):  
K031040.

Device Name:  
TheriFil™ Bone Void Filler

Indications for Use:  
TheriFil™ Bone Void Filler is indicated for use in filling the gaps or voids of osseous defects surgically created or resulting from trauma and intended for treatment of osseous defects not intrinsic to the stability of the bone structure. The product is intended for use in defects of the skeletal system (i.e., the extremities, spine and pelvis). TheriFil™ parts create an interlocking network within the defect site that resorbs during healing and is replaced by bone

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

Prescription Use   
(Per 21 C.F.R. 801.109)

510(k) Number K031040  
OR Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)